REMARKS

Claims 1 and 4-15 were presented for examination and were rejected.

The applicants have canceled claims 1 and 4-15, without prejudice, and reserve the right to re-add the canceled claims in this or in another application.

The applicants have replaced claims 1 and 4-15 with new claims 16-27 that relate to a method imparting spiral flow on blood passing through blood flow tubing. In particular, the subject matter of canceled claim 1 has been rewritten to relate to a method, now appearing as claim 16. Dependent claims 17-27 are based on those previously on file but have been correspondingly drafted to reflect the subject matter of claim 16.

Support for a method as defined in claims 16-27 can be found on page 2, lines 15 to 19 of the published PCT application.

The applicants respectfully submit that the new claims overcome the rejections and request reconsideration in light of the following comments.

35 U.S.C. 102 Rejection of Claims 1, 4-6, and 8-15

Claims 1, 4 through 6, and 8 through 15 were rejected under 35 U.S.C. 102(b) as being anticipated by P.J. Buscemi et al, U.S. Patent No. 5,500,013 (hereinafter "Buscemi"). The applicants respectfully submit that the amended claims overcome the rejection.

New claim 16 recites:

> **16.** A method of imparting spiral flow on blood passing through blood flow tubing comprising the step of providing within the blood flow tubing a helical formation formed from a biocompatible material and comprising an elongate member defining at least a portion of a helix wherein the elongate member comprises an inwardly extending portion which extends along the length of the elongate member, the inwardly extending portion extending inwardly from the internal side walls of the blood flow tubing for a distance equal to between 40% and 60% of the distance from the longitudinal axis of the blood flow tubing to an internal side wall.

The Office action has cited Buscemi essentially on the grounds that it discloses a coiled stent 50 having a camber 60 which extends inwardly and the distance from the longitudinal axis of the conduit in which the stent is located can be up to 50% depending upon the size of the vessel in which the stent is provided. However, the human body is clearly highly variable both from patient to patient and from blood vessel to blood vessel.

In other words, there is no positive indication in Buscemi that the camber 60 should be of a size to be up to 50% distance from the side wall to the longitudinal axis of the blood vessel in which it is located. Therefore, the applicants respectfully submit that a skilled person would not understand the teaching of Buscemi to include such a feature.

However, even if the Office's contention could be accepted, it is only a general teaching of all possible distances from the side wall of the blood vessel to the longitudinal axis of the blood vessel. However, the applicants respectfully point out that the amended claims recite a specific feature of "between 40% and 60%". Since the general does not anticipate the specific, the applicants respectfully submit that the pending claims are novel over Buscemi.

In addition, the pending claims relate to "a method of imparting spiral flow on blood" whereas this is not a method which is disclosed in Buscemi. Instead, as is stated in column 1, lines 13 to 15 of Buscemi, the stent is "for providing a mechanical support and a uniform release of drugs to a vessel lumen of a living being" which is not the same as imparting spiral flow on blood. Therefore the present invention as defined in the pending claims is novel over Buscemi.

For these reasons, the applicants submit that the rejection of claim 1 is overcome via new claim 16. Since new claims 17 through 27 depend on new claim 16, the applicants submit that the rejection of the dependent claims is also overcome.

35 U.S.C. 102 Rejection of Claims 1 and 4-10

Claims 1 and 4 through 10 were rejected under 35 U.S.C. 102(b) as being anticipated by P.N. Sawyer, US Patent No. 5,108,417 (hereinafter "Sawyer"). The applicants respectfully submit that the amended claims overcome the rejection.

Similar arguments apply to Sawyer as in relation to Buscemi discussed above. The Office refers to an inwardly extending portion near items 150 or 160 in Figures 2 and 3 of Sawyer. However, there is no teaching in Sawyer that these components should extend inwardly for a distance equal to between 40% and 60% of the distance from the longitudinal axis of the blood flow tubing to the internal side wall thereof. The argument presented in the Office action that the distance that the inwardly extending portion extends inwardly "can include up to 50% depending upon the size of the vessel the member is provided in" is only a statement of what Sawyer "can" disclose but not what it does disclose.

Even if the Office's contention could be accepted, it is only a general disclosure of the sizing of the component in Sawyer and not a specific distance range as recited in the amended claims.

Furthermore, Sawyer does not relate to imparting spiral flow on blood. On the contrary, Sawyer discloses movement of blood parallel to the axis of a blood vessel in the direction of the arrow A in Figures 2 and 3 (see column 4, lines 29 to 31). Sawyer describes the blood moving over the "air foil configuration" of the stent "in the same manner as air flows over the wing of an airplane", (see column 4, lines 26 to 29) and not in a spiral manner.

For these reasons, the applicants submit that the claims are novel over Sawyer.

35 U.S.C. 102 Rejection of Claims 1 and 6-10

Claims 1 and 6 through 10 were rejected under 35 U.S.C. 102(b) as being anticipated by H. Kojima, U.S. Patent No. 4,747,697 (hereinafter "Kojima"). The applicants respectfully submit that the amended claims overcome the rejection.

With respect to Kojima, the pending claims are clearly novel over Kojima since Kojima relates to fluid mixers in fields such as "chemical plants, food industry, environmental pollution prevention technology, electronics industry" (column 1, lines 10 to 13) and therefore does not relate to "a method of imparting spiral fluid on blood passing through blood flow tubing...." as is recited in new claim 16 of the amended set of claims.

For this reason, the applicants respectfully submit that the rejection of claim 1 is overcome via new claim 16. Because claims 17 through 27 depend on claim 16, the applicants respectfully submit that the rejection of the dependent claims is also overcome.

35 U.S.C. 103 Rejection of Claims 1, 4-8, and 11-15

Claims 1, 4 through 8, and 11 through 15 were rejected under 35 U.S.C. 102(b) as being anticipated by Simon, US Patent No. 5,924,456 (hereinafter "Simon"). The applicants respectfully submit that the amended claims overcome the rejection.

The tubular section member disclosed in Simon is clearly for use in an industrial context such as "for fluid flow in a motor vehicle, as an admission or exhaust silencer on a heat engine or on a pneumatic machine, and as a ventilation duct in buildings, structures, ships etc." (see column 4, lines 37 to 40 of Simon). There is thus no disclosure of imparting spiral flow on blood passing through blood flow tubing. As also observed in the Office

action, there is no disclosure in Simon of the helical formation being formed of a biocompatible material as in the amended claims.

Additionally, the arrangement disclosed in Simon is inherently inappropriate for use in blood flow tubing due to its construction blocking the majority of the lumen of the conduit. Referring to Figures 1 to 8, it can be seen that a substantial portion of the internal diameter of the conduit of Simon is taken up with the ribs 12 and axial core 16 of the conduit and would clearly pose an unacceptable risk of thrombus if used in blood flow tubing.

Furthermore, the helical section members disclosed in Simon are for a completely different purpose, namely to attenuate transmission of sound in fluids flow along tubes (see column 1, lines 11 to 12). This is not a problem that arises in blood passing through blood flow tubing and therefore a skilled person would have no reason to apply the components of Simon to the field of blood flow tubing.

For these reasons, the applicants submit that the claims are patentable over Simon.

35 U.S.C. 103 Rejection of Claims 1, 4-6, 8, and 11

Claims 1, 4 through 6, 8, and 11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhlmann DE 597,472 (hereinafter "Kuhlmann"), in view of Kojima.

Kojima has been discussed above and explained that it does not relate to a medical context. The applicants also respectfully point out that Kojima relates to the mixing of two or more kinds of fluids (see abstract) rather than imparting spiral flow on blood, which is a single type of fluid.

Kuhlmann also does not relate to imparting spiral flow on blood since it does not relate to the medical field but apparently relates to industrial applications since it talks of gaseous, liquid or powdery media (referring to its claims).

Therefore, even if a skilled person were to combine the teachings of Kojima and Kuhlmann, he would not arrive at the invention defined in the amended claims, which relate to imparting spiral flow on blood passing through blood flow tubing, because neither document relates to blood passing through blood flow tubing.

For these reasons, the applicants submit that the claims are patentable over Kuhlmann, in view of Kojima.

35 U.S.C. 103 Rejection of Claims 7, 9, 10, and 12-15

Claims 7, 9, 10, and 12 through 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhlmann, in view of Kojima, and further in view of Tayside, EP 1,254,645, (hereinafter "Tayside").

Each of the cited documents relates to a different context and has a different purpose. With respect to different context, as explained above Kojima relates to the mixing of two different kinds of fluid. Kuhlmann relates to conferring helically directed flow in order to maximize the heat emission from the flow medium to the walls of the pipe (see paragraph 2 of Kuhlmann). Tayside relates to a eliminating or reducing turbulence in blood flow tubing (see paragraph [0008]). Therefore, Tayside relates to a different technical field (the medical field and, more specifically, blood flow tubing) as compared to Kuhlmann and Kojima, which relate to the industrial context.

Additionally, Kojima addresses the problem of mixing two fluids, Kuhlmann addresses the problem of heat emission of fluids, and Tayside addresses the problem of reducing turbulence of a fluid. Thus each addresses a different problem. Because of the different contexts and purposes involved, it would not have been obvious for a skilled person to combine the teachings of these three documents.

Moreover, the documents would tend to lead a skilled person away from combining their teaching. Tayside teaches (see paragraph [0003]) that spiral blood flow in peripheral arteries has implications for the pathogenesis of atherosclerosis and intimal hyperplasia. However, it would not be obvious that the disclosure in Kuhlmann or Kojima of helical components extending into the lumen of the conduit as far as they propose would be suitable for using in blood flow tubing due to the risk of occluding the blood flow tubing altogether. In this regard, the applicants refer to Figure 2 of Kuhlmann and Figures 16 and 17 of Kojima in which it is clear that the lumen of the conduit is substantially narrowed. A person skilled in the field of the invention of Tayside (pathologies of the blood circulation) would tend to assume that providing the helical formation at this size would be detrimental to a patient as there would be an unacceptably high risk of blockage of the blood flow tubing. Indeed, the main desire for a skilled person would be to minimize the presence of any components within the blood flow tubing and therefore to disregard the teaching of Kuhlmann or Kojima. Accordingly, it would not have been obvious for a person skilled in the art to combine the disclosures of Tayside, Kuhlmann, and Kojima in order to produce the present invention.

For these reasons, the applicants submit that the claims are patentable over Kuhlmann, in view of Kojima, and further in view of Tayside.

Request for Reconsideration Pursuant to 37 C.F.R. 1.111

Having responded to each and every ground for objection and rejection in the Office action mailed June 6, 2007, applicants respectfully request reconsideration of the instant application pursuant to 37 CFR 1.111 and request that the Examiner allow all of the pending claims and pass the application to issue.

If there are remaining issues, the applicants respectfully request that Examiner telephone the applicants' attorney at 732-578-0103 x12 so that those issues can be resolved as quickly as possible.

Respectfully,
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